



**DEPARTMENT OF TRANSPORTATION**

**[4910-EX-P]**

**Federal Motor Carrier Safety Administration**

**[Docket No. FMCSA-2018-0320]**

**Qualification of Drivers; Exemption Applications; Narcolepsy**

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of denial.

**SUMMARY:** FMCSA announces its decision to deny the application from one individual who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting operation of a commercial motor vehicle (CMV) in interstate commerce by persons with either a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to control a CMV, or a mental, nervous, organic, or functional disease or psychiatric disorder likely to interfere with his/her ability to drive a commercial motor vehicle safely.

**FOR FURTHER INFORMATION CONTACT:** Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, [fmcamedical@dot.gov](mailto:fmcamedical@dot.gov), FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

**SUPPLEMENTARY INFORMATION:**

**I. Public Participation**

**A. Viewing Documents and Comments**

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to <http://www.regulations.gov>. Insert the docket number, FMCSA-

2018-0320, in the keyword box, and click “Search.” Next, click the “Open Docket Folder” button and choose the document to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

## **B. Privacy Act**

In accordance with 5 USC 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at [www.dot.gov/privacy](http://www.dot.gov/privacy).

## **II. Background**

On November 27, 2018, FMCSA published a FR notice (83 FR 60953) announcing receipt of an application from one individual with a diagnosis of narcolepsy and requested comments from the public. This individual requested an exemption from 49 CFR 391.41(b)(8), which prohibits operation of a CMV in interstate commerce by persons with either a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to control a CMV, and 49 CFR 391.41(b)(9) a mental, nervous, organic, or functional disease or psychiatric disorder likely to interfere with his/her ability to drive a CMV safely. The public comment period closed on December 27, 2018. Four comments were received in response to this proceeding. Of the four comments received, two were duplicate comments received from the applicant, and one comment was received from a private citizen. These commenters were in support of granting an exemption based on the applicant’s driving history. The fourth commenter, the American Academy of Sleep

Medicine (AASM) commented that the Agency should not grant an exemption for narcolepsy and outlined nine specific reasons for their non-support. Details of the AASM's comments may be found in the docket under the comments section.

FMCSA has evaluated the eligibility of this applicant and concluded that granting the exemption would not provide a level of safety that would be equivalent to, or greater than, the level of safety that would be obtained by complying with the regulation 49 CFR 391.41(b)(8) and (b)(9).

In reaching the decision to deny these exemption requests, the Agency considered information from the 2009 Evidence Report, "Narcolepsy (with and without cataplexy) and Commercial Motor Vehicle Driver Safety<sup>1</sup>," and the January 2010 Medical Review Board (MRB) Recommendation<sup>2</sup> that individuals with narcolepsy be ineligible for a commercial driver's license, even with treatment. A copy of the Evidence Report is included in the docket.

### **III. Basis for Exemption Determination**

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs if the exemption is likely to achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

The Agency's decision regarding these exemption applications is based on an individualized assessment of each applicant's medical information provided by the applicant, available medical and scientific data concerning narcolepsy, and public comments received. As discussed in the background section, the Agency considered information from the 2009 Evidence Report, "Narcolepsy (with and without cataplexy) and Commercial Motor Vehicle

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<sup>1</sup> Evidence Report: Narcolepsy (with and without cataplexy) and Commercial Motor Vehicle Driver Safety; October 6, 2009

<sup>2</sup> Medical Review Board Meeting; January 6, 2010;  
[www.mrb.fmcsa.dot.gov/documents/Final\\_Jan\\_6\\_2010\\_MRB\\_Meeting\\_Summary.pdf](http://www.mrb.fmcsa.dot.gov/documents/Final_Jan_6_2010_MRB_Meeting_Summary.pdf)

Driver Safety,” and the January 2010 recommendation that individuals with narcolepsy be ineligible for a commercial driver’s license, even with treatment.

FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5.] The advisory criteria for 49 CFR 391.41(b)(8), indicates that if an individual has had a sudden episode of a non-epileptic seizure or loss of consciousness of unknown cause that did not require anti-seizure medication, the decision whether that person's condition is likely to cause the loss of consciousness or loss of ability to control a CMV should be made on an individual basis by the medical examiner in consultation with the treating physician.

In those individual cases where a driver had a seizure or an episode of loss of consciousness that resulted from a known medical condition (e.g., drug reaction, high temperature, acute infectious disease, dehydration, or acute metabolic disturbance), certification should be deferred until the driver has fully recovered from that condition, has no existing residual complications, and is not taking anti-seizure medication.

The advisory criteria for 49 CFR 391.41(b)(9), indicates that a variety of functional disorders can cause drowsiness, dizziness, confusion, weakness or paralysis that may lead to incoordination, inattention, loss of functional control and susceptibility to accidents while driving.

Narcolepsy is a chronic neurological disorder caused by autoimmune destruction of hypocretin-producing neurons inhibiting the brain's ability to regulate sleep-wake cycles normally. Persons with narcolepsy experience frequent excessive daytime sleepiness, comparable to how non-narcoleptics feel after 24 to 48 hours of sleep deprivation, as well as

disturbed nocturnal sleep, which is often confused with insomnia. See National Institutes of Health (NIH) Narcolepsy Fact Sheet at [www.ninds.nih.gov/disorders/narcolepsy/detail\\_narcolepsy.htm](http://www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm).

The 2009 Evidence Report, “Narcolepsy (with and without cataplexy) and Commercial Motor Vehicle Driver Safety,” addressed whether or not individuals with narcolepsy are at an increased risk for motor vehicle crashes; whether or not currently recommended treatments for narcolepsy reduce the risk for motor vehicle crashes; and the impact of various medication therapies for narcolepsy on driver safety.

The evidence report reviewed studies from the available literature and evaluated outcomes on measures of Excessive Daytime Sleepiness (EDS), cataplexy, event rate, measures of cognitive and psychomotor function, and driving performance. The currently available direct and indirect evidence support the contention that drivers with narcolepsy are at an increased risk for a motor vehicle crash when compared to otherwise similar individuals who do not have the disorder. The direct evidence from three crash studies conducted of non-CMV drivers showed that individuals with narcolepsy are at an increased risk for a crash compared to individuals who do not have narcolepsy. The indirect evidence from studies of driving tests and driving simulation examined factors associated with simulated driving outcomes such as driving performance, tracking error, fewer correct responses, and more instances of going out of bounds compared to healthy controls. While there are limitations in the quality of the studies that examined direct crash risk, both the direct and indirect studies showed a strong effect size and statistical significance. The American Academy of Sleep Medicine (AASM) and the European Federation of Neurological Societies recommend modafinil as the first treatment option and methylphenidate as the second treatment option. The AASM also recommends amphetamine, methamphetamine, or dextroamphetamine as

alternative treatments. During literature searches, no studies that directly examined the impact of treatment with modafinil, armodafinil, sodium oxybate (used with narcolepsy with cataplexy), or anti-depressants on crash risk or driving performance were identified. Therefore, conclusions regarding treatment with these medications on crash risk and driving performance could not be made.

Currently available evidence suggests that amphetamines and/or methylphenidate are effective in improving symptoms of EDS in individuals with narcolepsy (quality of studies range from “moderate to low”). However, these improvements do not result in levels of daytime sleepiness that can be considered to be normal in the vast majority of individuals. Therefore, conclusions regarding to the impact of treatment with amphetamines, methylphenidate, or other related stimulant drugs on cognitive and psychomotor function among individuals with narcolepsy could not be made.

In January 2010, the FMCSA’s MRB recommended that individuals with narcolepsy be ineligible for a commercial driver’s license, even with treatment.

#### **IV. Conclusion**

The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting these exemptions would achieve a level of safety equivalent to, or greater than, the level of safety maintained without the exemption. Therefore, the applicant, Terry L. Curtner (IL), has been denied an exemption from the physical qualification standards in 49 CFR 391.41(b)(8) and (b)(9):

The applicant has, prior to this notice, received a letter of final disposition regarding his exemption request. The decision letter fully outlined the basis for the denial and constitutes final action by the Agency. The applicant's information published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

**Issued on:** March 20, 2019.

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Larry W. Minor,  
*Associate Administrator for Policy.*